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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR          | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|-------------------------------|-------------------------------|------------------|
| 10/058,622  | 01/28/2002  | Charles Achim Bernard Boucher | DVME-1014USCON1               | 4855             |
| 21302   | 7590        | 02/24/2004                    |                               |                  |
| KNOBLE, YOSHIDA & DUNLEAVY<br>EIGHT PENN CENTER<br>SUITE 1350, 1628 JOHN F KENNEDY BLVD<br>PHILADELPHIA, PA 19103 |             |                               | EXAMINER<br>MAHATAN, CHANNING |                  |
|   |             |                               | ART UNIT                      | PAPER NUMBER     |
|   |             |                               | 1631                          |                  |

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

**Office Action Summary****Application No.**

10/058,622

**Applicant(s)**BOUCHER, CHARLES ACHIM  
BERNARD**Examiner**

Channing S Mahatan

**Art Unit**

1631

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/902,624.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### *APPLICANTS' ARGUMENTS*

Applicants' arguments, filed 28 November 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 21-63. Claims 1-20 have been cancelled.

### *PRIORITY DOCUMENT*

It is acknowledged the certified copy of the priority document (European Patent Office (EPO) 00202482.6) was filed in the parent U.S. Patent Application No. 09/902,624.

### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

#### *LACK OF ENABLEMENT*

Claims 21-63 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record the rejection is maintained wherein this rejection was previously applied to claims 1-20 (cancelled) and is now herein directed to instant claims 21-63.

Applicants present the following arguments in the response filed 28 November 2003: 1) "the rules database is updated by a core committee that periodically reviews, on a frequent basis,

the latest publications on the subject and decides which adjustments should be made to the rules, based on these latest publications”; 2) “the core-committee assigns a value indicating the resistance level”; 3) “the core-committee will assign the confidence level by reading the scientific articles and determining which of the confidence applies”; 4) “the suitability level is the outcome of the review of all information on resistance level, drug level, confidence level and clinical experience presented to the core-committee and is based upon knowledge of the expert members of the core-committee and their review of all of this information”; 5) “the claims do not require specific rules, but only the use of a set of rules having certain characteristics, and these characteristics as such are known to the skilled person”; and 6) “no specific algorithm/steps/procedures are required for derivation of the first, second, and third values, other than that the skilled person take into consideration certain information, as specified in the claims, in deriving those values”. Applicants’ assert that support for the above arguments can be found on page 3, line 31 to page 4, line 18; page 3, line 31 to page 5, line 11; page 4, lines 15-18; and page 5, line 35 up to page 6, line 6. Applicants’ arguments are unpersuasive.

In fact, Applicants’ arguments appear to support the Examiner’s conclusions in the previous office action mailed 29 July 2003:

“The specification fails to provide guidance as to how the rules database is: 1) updated reflecting the latest publications on the subject; 2) how the conferred resistance by substitution is derived and then assigning a value indicative of resistance level; 3) how evidence in the scientific literature is assigned to indicate confidence level; 4) how to combine and weigh resistance level, drug level, confidence level, clinical experience to assign a value indicative of suitability. Additionally, it is unclear how clinical experience can be assessed and utilized to determine suitability. Absent from the specification are any algorithms/steps/procedures for the derivation of

the first, second, and third values by conferred resistance, scientific literature, and the combination of resistance level, drug level, confidence level, and clinical experience.”

wherein Applicants’ arguments assert that the core-committee is to perform all of the above functions. However, absent from the specification are the guidelines/decisions by which the core-committee is to perform the above functions. For instance, by what manner/procedures (i.e. the steps of analysis/assessment/evaluation) does the core-committee review publications? What parameters define the decision process so that adjustments can be made to the rules? One of skill in the art would be unable to assess the scientific literature without a set of guidelines by which to follow. The derivation of said “rules” is considered undue because it is unclear what the core-committee is performing procedurally with respect to the scientific literature and assignment of values. The derivation of said “rules” is not considered routine in the art and would required further inventive skill to develop said “rules”. Thus, the original disclosure fails to provide one of skill in the art proper guidance to make and/or use the claimed method, computer program device, and computer program carrier.

Applicants state “The claims cover any method for assigning these values that involves use of the information specified in the claims, and a skilled person, exercising common general knowledge, is capable of assigning these values without requiring further guidance from the present application”, and are therefore requested to provide support for such an assertion. Additionally, the instant claims do not recite a “core-committee” to perform the task of updating the database, evaluating, and assigning values (i.e. resistance level, confidence level, and suitability) based upon review of scientific literature as presented in Applicants arguments. It should be noted that such language, if amended into the instant claims, may be viewed as an

abstract concept/idea and may result in a rejection under 35 U.S.C. § 101 Non-Statutory Subject Matter.

*ACTION IS FINAL*

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *February 18, 2004*  
Examiner Initials: *ESM*

*Marianne P. Allen*  
**MARIANNE P. ALLEN**  
**PRIMARY EXAMINER**  
*A41631*